

	UNIVERSITY OF MALTA FACULTY OF MEDICINE & SURGERY PHARMACY DEPARTMENT	Ref. No. SOP/PD/226_01
	STANDARD OPERATING PROCEDURE	
	MULTICARE-IN®	Valid for: 2 years from approval

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1. Scope

This Standard Operating Procedure (SOP) applies to the staff and students using the multiCare[®]-In in the Pharmacy Practice Resource Unit (PPRU) at the Pharmacy Department, University of Malta.

2. Objective

To describe the procedure for set-up, configuration, operation, recording and recalling of results, quality control, maintenance and troubleshooting of the multiCare[®]-In

3. Definitions

3.1. Control solution: Used to check the proper functioning of the device to ensure reliable results. Checking with control solution should be carried out before device is used for the first time, when starting a new box of test strips, when inserting a new battery, following a cleaning procedure, after accidentally dropping the device and when results do not coincide with clinical symptoms. The control solution must be used within 90 days from first opening. The result obtained with the control solution must be deleted from memory not to interfere with the average test result.

3.2. EC: Icon indicating that code chip is inserted into the device.

3.3. Memory Mode: multiCare[®]-In stores up to 500 test results for each parameter. The results, including date and time, will be saved in memory (position 1) and results previously obtained will be saved in positions 2, 3 and so on, starting from the most recent.

3.4. multiCare[®]-In device: Measures concentration of the parameters glucose (GLC), cholesterol (CH) and triglycerides (TGL) in whole blood using test strips specific to each parameter. Each box of test strips has a unique code chip.

3.5. Reactive Area: Circular white area where the blood sample is applied

3.6. Settings Mode: Allows setting of date and time, units of measurements, average of results, acoustic signal and alarms.

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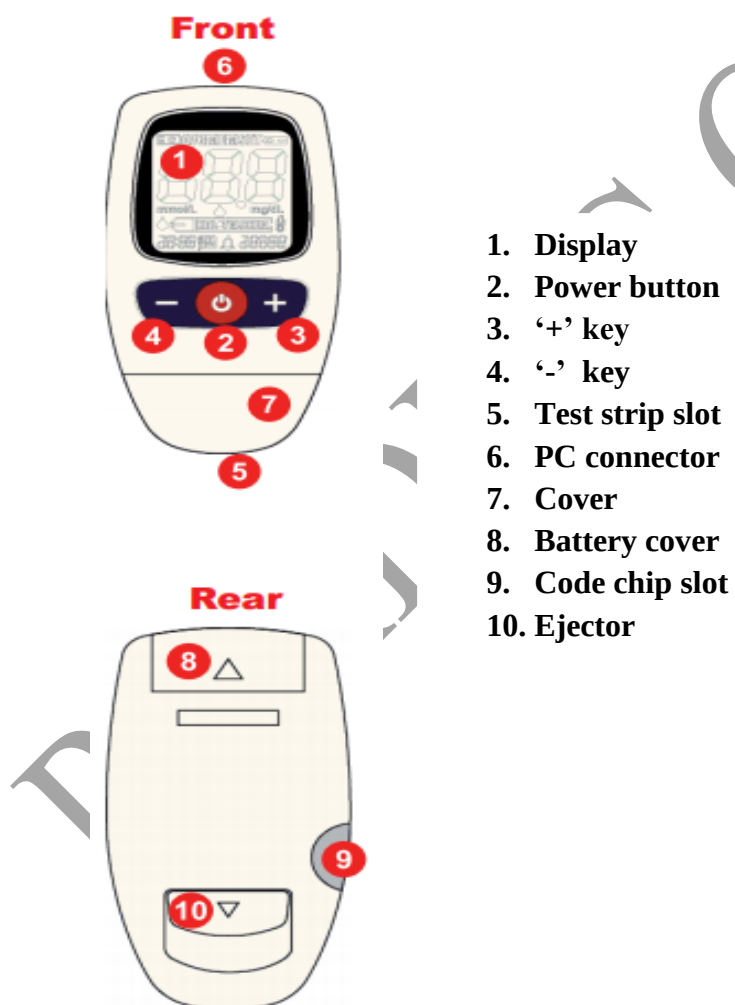
4. Responsibility

4.1. The members of the Department of Pharmacy (staff and students) are responsible for following this SOP.

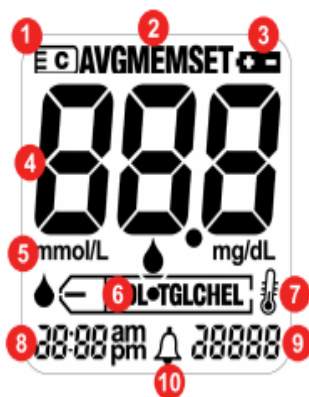
4.2. The designated Laboratory Officer or Laboratory Assistant is responsible for ensuring that this SOP is followed.

5. Procedure

5.1. Diagram



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1. Code-chip inserting
2. Device mode
3. Low battery warning
4. Test results and messages
5. Unit of measurement
6. Test analytes
7. Abnormal temperature warning
8. Time
9. Day and month
10. Alarm

5.2. Set-Up: General Settings

5.2.1. Place batteries in the battery compartment.

5.2.2. Turn device 'On' using power button.

5.2.3. Press and hold power button to enter 'Settings Mode'; 'SET' will appear in the display and the date will blink.

5.2.4. Setting Date and Time

5.2.4.1. Use '+' and '-' keys to adjust the month and press power button to confirm.

5.2.4.2. Use '+' and '-' keys to adjust the day and press power button to confirm.

5.2.4.3. The month and day blink simultaneously; Use '+' and '-' keys to select preferred visualisation of date configuration (MM/DD or DD/MM) and press power button to confirm.

5.2.4.4. Use '+' and '-' keys to adjust the year and press power button to confirm.

5.2.4.5. Use '+' and '-' keys to adjust the hour and press power button to confirm.

5.2.4.6. Use '+' and '-' keys to adjust the minutes and press power button to confirm.

5.2.4.7. The time blinks and 12h appears on the display; Use '+' and '-' keys to select preferred visualisation of time configuration (12h or 24h) and press power button to confirm.

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5.2.5. *Setting the Units*

- 5.2.5.1. The unit of measurement 'mg/dL' blinks on the display; Use '+' and '-' keys to select unit of measurement (mg/dL or mmol/L) and press power button key to confirm.

5.2.6. *Setting the Average of Results*

- 5.2.6.1. '0' starts blinking and 'days AVG' appears on the display; Use '+' and '-' keys to select 7, 14, 21, or 28 days and press power button to confirm.

5.2.7. *Setting the Acoustic Signal*

- 5.2.7.1. BP appears on the display; Use '+' and '-' keys to select the acoustic signal on (enabled) or off (disabled) and press power button key to confirm.

5.2.8. *Setting the Alarms*

- 5.2.8.1. '0' blinks on the display; Use '+' and '-' keys to select alarm number to be enabled (0, 1, 2 or 3) and press power button to select hour and minutes (alarm).

5.2.9. Press power button to exit 'Settings Mode'.

5.3. **Performing a Measurement**

- 5.3.1. Insert code chip.
- 5.3.2. Switch the device 'On'; code chip number, parameter symbol (GLC, CH, TGL) and EC will show on the display.
- 5.3.3. Take a test strip from the container and close container immediately.
- 5.3.4. Insert test strip in 'test strip slot' with the side indicating the printed initials of the parameter at the top.
- 5.3.5. Push test strip inwards until a click is heard; a symbol showing a drop of blood appears after about 1.5 seconds if test strip is inserted correctly (the blood drop can be applied with the test strip inserted in the device).
- 5.3.6. Obtain a capillary blood sample from the fingertip (3µL for GLC and at least 10µL for CH and TGL).
- 5.3.7. Discard the first drop of blood.

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5.3.8. Place the second drop on the reactive area, saturating it completely. The result will be displayed after a few seconds.

5.3.9. Perform a control test if result is out of range, too high (Hi) or too low (Lo); refer to section 5.4.

5.3.10. Turn device 'Off' when test is complete or device will shut down automatically after 1.5 minutes.

5.4. Performing a Control Test

5.4.1. Follow section 5.3 using the control solution instead of a blood sample.

5.4.2. Compare the result with the range shown on the label of the test strip container.

5.5. Memory

5.5.1. *Recalling Memory*

5.5.1.1. Turn device 'On' using power button.

5.5.1.2. Press and release '+' and '-' keys to enter 'Memory Mode' and the average of the test results will be displayed.

5.5.1.3. Press '+' and '-' keys to display memory number; if '+' and '-' keys are held down, the device scrolls quickly and only memory positions are displayed.

5.5.1.4. Release '+' and '-' keys to display corresponding result.

5.5.2. *Deleting Memory*

5.5.2.1. Press power button and '-' key for 1 second to delete one test result.

5.5.2.2. Press '-' key for 5 seconds together with the power button to delete all test results.

5.5.2.3. Press power button to confirm.

5.6. Enabling Data Transfer to a Computer

5.6.1. Install the software on the computer.

5.6.2. Insert serial port of the cable in the computer and the connector to the device.

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5.6.3. Press and release the power button; 'PC' will appear on the display and data is transferred.

5.6.4. Turn device 'Off' and remove the cable.

5.7. Changing the Battery

5.7.1. Slide the battery compartment outwards.

5.7.2. Remove the batteries.

5.7.3. Place the new batteries (2 CR 2032 batteries) with the positive side on top.

5.7.4. Close the back cover until a click is heard.

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5.8. Troubleshooting

	Error message	Problem	Solution
	E01	The temperature is lower than 5°C (41°F) or higher than 45°C (113°F).	Place the instrument in an area with temperature between 5°C(41°F) and 45°C (113°F) and wait for the instrument to equilibrate with the external temperature, before performing the measurement.
	E02	The strip is used or the reactive area is coloured.	Use a new strip to perform the measurement.
	E02	The strip is not correctly inserted.	Remove and insert the strip again, checking that it is plan on the plastic support of the instrument.
	E02	The blood was applied on the strip before waiting for the drop blinking on the display.	Take a new strip, insert it in the instrument and, only after visualized blinking drop on the display, apply the blood on the strip.
	E02	The plastic support or the reading window are dirty.	Pull out the plastic support where you insert the strip and clean the glass window using only water. Dry the glass without scratch it. Do not use solvents or soap. Insert the plastic support and repeat the test.
	E03	The strip is removed from the meter without applying the drop of blood.	Switch off the meter by ON/OFF button. Insert the strip again and apply the blood on the strip without remove the strip from the strip holder
	E04	The strip that you are using does not correspond to the parameter of the data-chip.	Remove the data-chip and use the one corresponding to the strip that you want to use and check that the parameter symbol on the display is the same of the one printed on the strip.

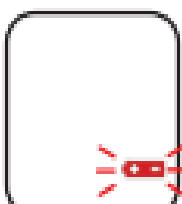
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Error message	Problem	Solution
E04	The strip is inserted upside-down.	Insert the strip again and be careful that the parameter symbol printed on the strip is on the upper part of the strip.
E05	Data-chip error.	Remove the data-chip and insert it again. If E05 still remains, contact Multicare customer Service.
E06	The blood is not enough.	Repeat the test and apply more blood.
E07	The data-chip is not inserted.	Insert the data-chip corresponding to the strips that you want to use.
LO	The result is lower than the limit of that parameter (see also instruction for use of the strips).	If the result does not correspond to the personal sensations, repeat the test. If LO is obtained again, contact your physician for additional information.
LO	In the case of parameters cholesterol and triglycerides, where blood's quantity to be applied has to be abundant, it is possible to obtain LO if the quantity of blood is under the limit of enough volume.	Repeat the test with a big quantity of blood. If LO is obtained again, contact your physician for additional information.



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	Error message	Problem	Solution
	HI	Value is higher than the limit of reading of that parameter.	Contact immediately your physician and repeat the test in an hospital.
		The batteries are almost flat. It is possible to perform about 30 measurements.	Get new batteries.
		The batteries are flat.	Replace the batteries before taking a measurement.
		The result is discontinuous when the strip has expired.	Check expiry date of the strips and use new strips to perform the measurements. Blinking result is not saved in the memory.

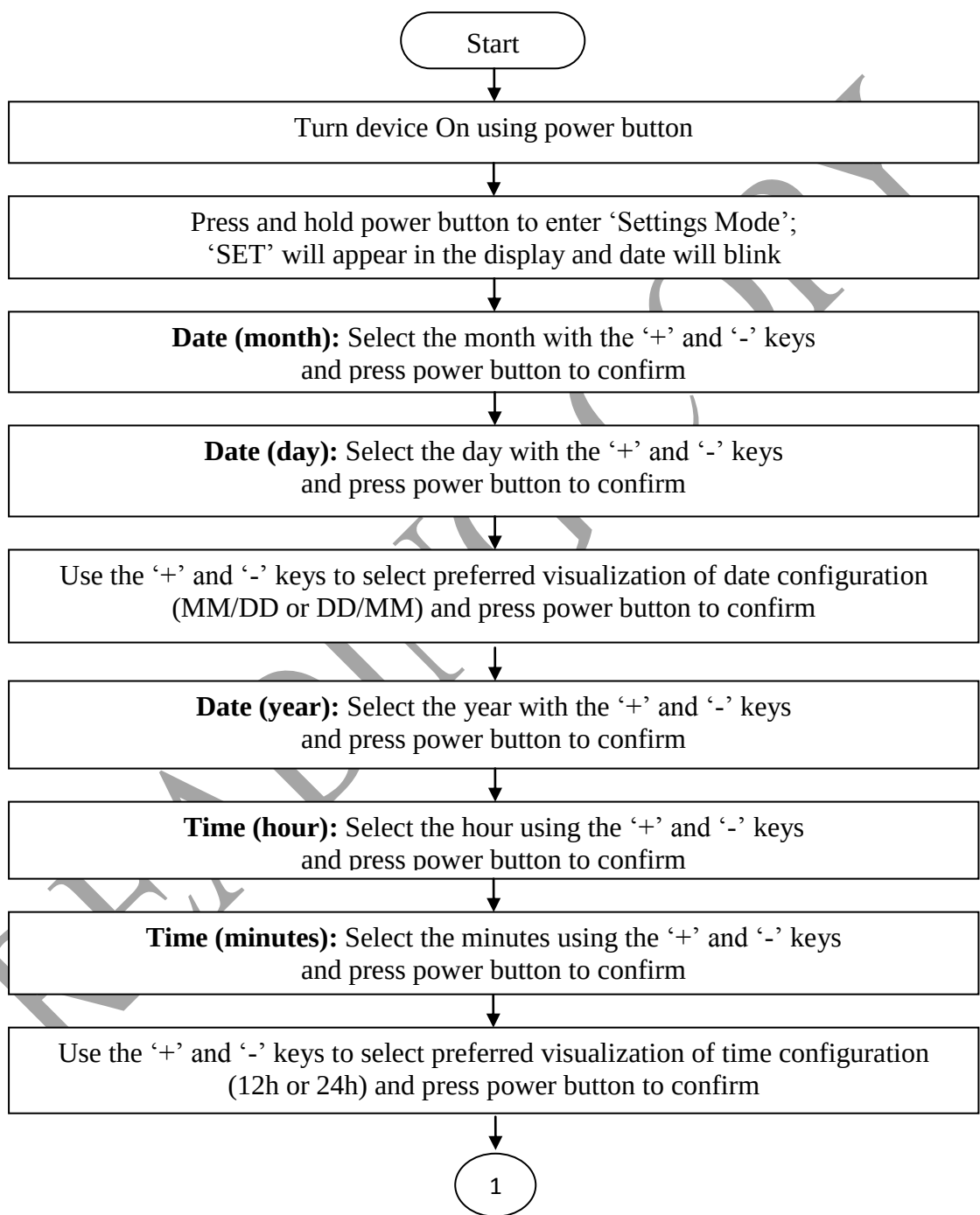
5.9. Care and Maintenance

- 5.9.1. Clean the device at least once a week using an alcohol swab.
- 5.9.2. Do not soak the device in cleaning agents.
- 5.9.3. Do not place device under running water.
- 5.9.4. Allow the device to dry naturally.

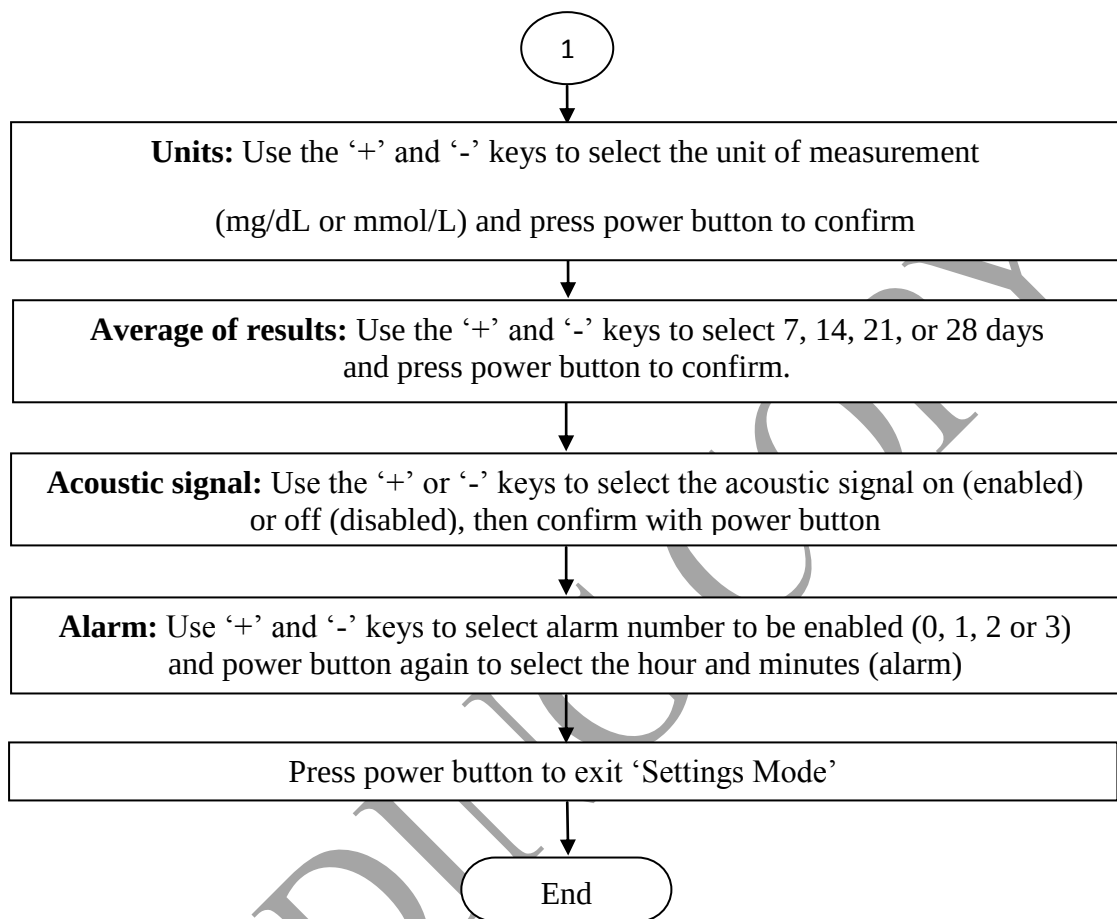
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5.10. Flowcharts

5.10.1. Set-Up: General Settings

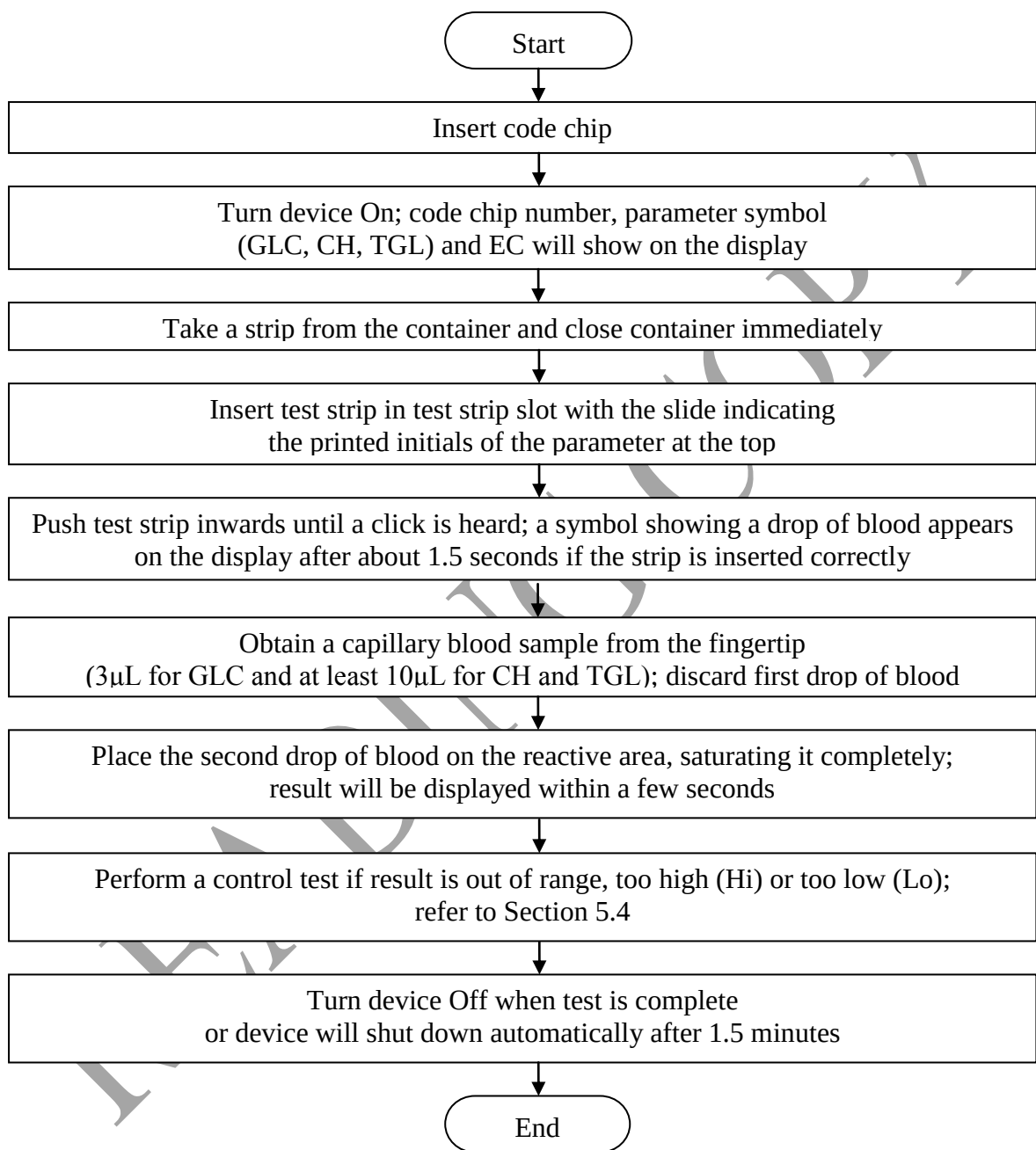


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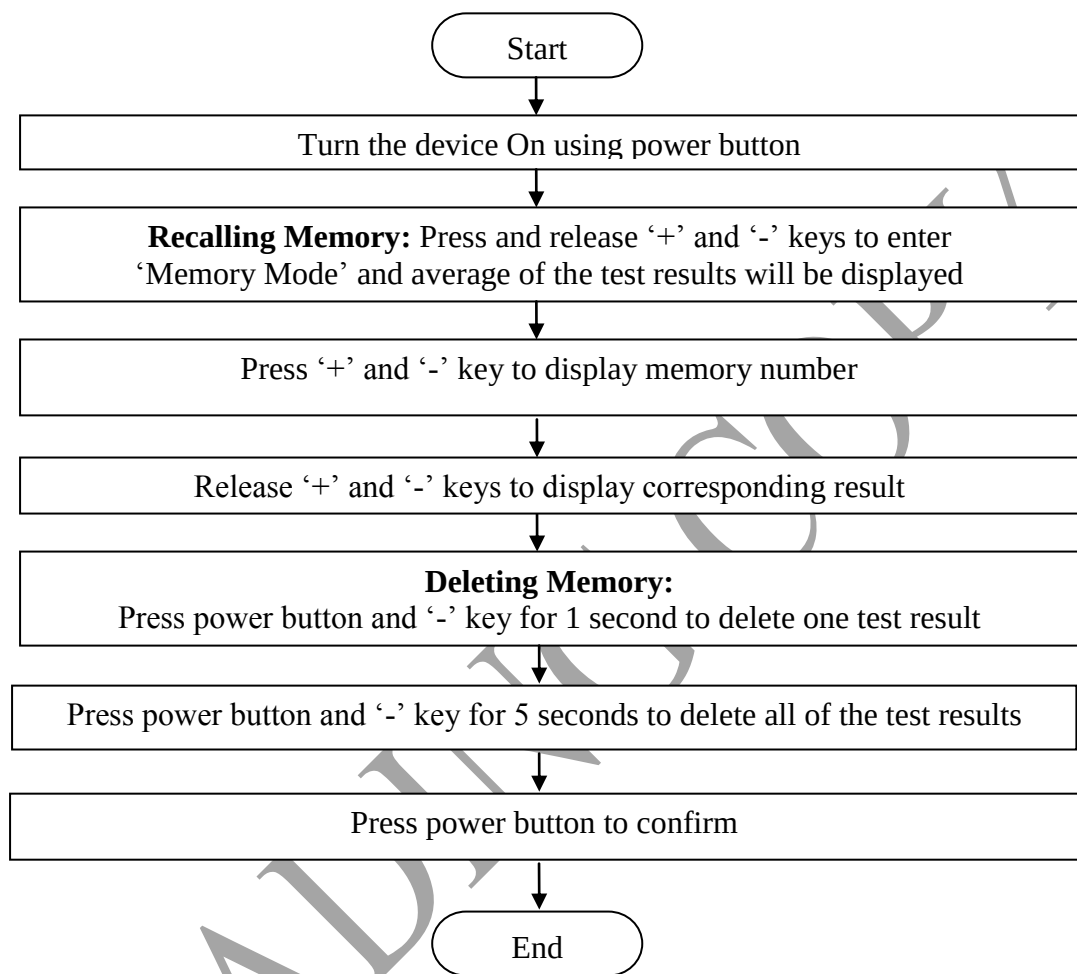
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5.10.2 Performing a Measurement



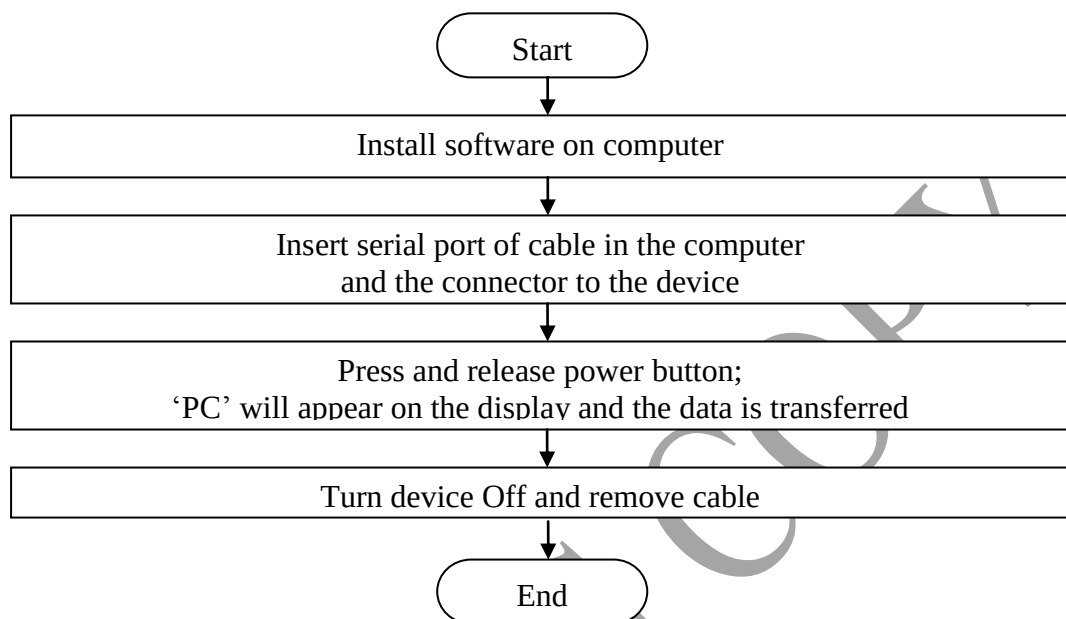
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5.10.3 Memory



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5.10.4 Enabling Data Transfer to a Computer



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6. Precautions

- 6.1. Replace old code chip with new code chip each time a new container of strips is used.
- 6.2. Check that the colour of the code chip and parameter symbol displayed on the device correspond to the parameter that needs to be measured.
- 6.3. Keep test strips in their original container away from direct sunlight and humidity and at a temperature between 10 – 35°C.
- 6.4. Close the test strip container immediately to avoid damage by humidity and light.
- 6.5. Do not use test strips after the expiry date.
- 6.6. Dispose used test strips and other blood-stained materials as biohazardous waste.
- 6.7. Keep the control solution at room temperature (10 – 35°C).
- 6.8. Do not use the control solutions to clean the device.
- 6.9. Do not keep the device at temperatures below -25°C or above 60°C.
- 6.10. Turn the device off before removing the battery.

7. Reference

Biochemical Systems International. multiCare[®]-In User Manual. Arezzo, Italy; 2008.

8. Appendices

N/A

9. Revision History

Version Number	Amendments/ Reasons for change
01	Initial Release